



4. Given admits that Given Imaging Ltd. is an Israeli corporation, with a principal place of business at 2 Hacarmel Street, New Industrial Park, Yoqneam 20692 Israel. Given denies the remaining allegations contained in Paragraph 4 of the Complaint.

5. Given admits that Given Imaging, Inc. is a Delaware corporation with a principal place of business at 3950 Shackleford Road, Suite 500, Duluth, Georgia 30096-1852, and is a wholly-owned subsidiary of Given Imaging Ltd. Given denies the remaining allegations contained in Paragraph 5 of the Complaint.

### **JURISDICTION AND VENUE**

6. Given admits that the Complaint purports to state an action arising under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, Title 28 of the United States Code, and purports to state that this Court has subject matter jurisdiction over this action. Given does not contest subject matter jurisdiction. Given denies the remaining allegations contained in Paragraph 6 of the Complaint.

7. Given does not contest that this Court has personal jurisdiction over Given in this action. Given denies the remaining allegations contained in Paragraph 7 of the Complaint.

8. Given does not contest that venue is proper. Given denies the remaining allegations contained in Paragraph 8 of the Complaint.

### **COUNT 1 – CLAIM FOR PATENT INFRINGEMENT OF U.S. PATENT NO. 5,010,412**

9. Given repeats and incorporates by reference its responses to the allegations contained in Paragraphs 1-8 above, as if fully set forth herein.

10. Given admits that U.S. Patent No. 5,010,412 (“the ’412 patent”) states on its face that it issued on April 23, 1991 to Gregory M. Gariss and is entitled “High Frequency,

Low Power Light Source For Video Camera.” Given denies that the patent was “duly and legally issued” and denies the remaining allegations contained in Paragraph 10 of the Complaint.

11. Given is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 11 of the Complaint, and therefore denies them.

12. Given admits that The Boeing Company identified to Given the ’412 patent. Given denies the remaining allegations contained in Paragraph 12 of the Complaint.

13. Given is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 13 of the Complaint, and therefore denies them.

14. Given admits that Given Imaging Ltd. has (or has caused to be) manufactured, imported into the United States and/or exported to the United States, capsule endoscopes with a light source, and continues to do so. Given also admits that it does so without permission from Olympus Medical because such permission is not required. Given denies any direct infringement, inducement of infringement, or contributory infringement of the ’412 patent, and the remaining allegations contained in Paragraph 14 of the Complaint.

15. Given admits that Given Imaging, Inc. has (or has caused to be) sold in the United States, capsule endoscopes with a light source, and continues to do so. Given also admits that it does so without permission from Olympus Medical because such permission is not required. Given denies any direct infringement, inducement of infringement, or contributory infringement of the ’412 patent, and the remaining the allegations contained in Paragraph 15 of the Complaint.

16. Given denies the allegations contained in Paragraph 16 of the Complaint.

17. Given denies the allegations contained in Paragraph 17 of the Complaint.

18. Given denies the allegations contained in Paragraph 18 of the Complaint.

**COUNT 2 – CLAIM FOR DECLARATORY JUDGMENT OF NONINFRINGEMENT  
AND INVALIDITY**

19. Given repeats and incorporates by reference its responses to the allegations contained in Paragraphs 1-18 above, as if fully set forth herein.

20. Given admits the allegations contained in Paragraph 20 of the Complaint.

21. Upon information and belief, Given admits the allegations contained in Paragraph 21 of the Complaint.

22. Given is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 22 of the Complaint, and therefore denies them.

23. Given is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 23 of the Complaint, and therefore denies them.

24. Given admits that it is the assignee of patents that, upon information and belief, Olympus's capsule endoscope and/or its associated system will infringe. Given denies the remaining allegations contained in Paragraph 24 of the Complaint.

25. Given admits that it is the assignee of patents that, upon information and belief, Olympus's capsule endoscope and/or its associated system will infringe. Given denies the remaining allegations contained in Paragraph 25 of the Complaint.

26. Given admits, and has informed the USPTO, that certain of Given's capsule endoscope products are covered by its patents, and that it was only after Given's imaging capsule was introduced that Olympus sought to market a "me-too" product. Given denies the remaining allegations contained in Paragraph 26 of the Complaint.

27. Given does not contest that an actual and justiciable controversy exists between Given and Olympus with respect to Given's '531 patent. Given denies the remaining allegations contained in Paragraph 27 of the Complaint.

28. Given denies the allegations contained in Paragraph 28 of the Complaint.

29. Given denies the allegations contained in Paragraph 29 of the Complaint.

30. Given denies the allegations contained in Paragraph 30 of the Complaint.

31. Given denies the allegations contained in Paragraph 31 of the Complaint.

## **II. DEFENSES**

### **FIRST AFFIRMATIVE DEFENSE – NO CAUSE OF ACTION**

1. The Complaint fails to state a claim upon which relief can be granted.

### **SECOND AFFIRMATIVE DEFENSE – NONINFRINGEMENT OF THE '412 PATENT**

2. Given does not infringe and has not infringed (either directly, contributorily or by inducement) any valid claim of the '412 patent.

### **THIRD AFFIRMATIVE DEFENSE – INVALIDITY OF THE '412 PATENT**

3. One or more claims of the '412 patent are invalid for failure to comply with one or more of the conditions and requirements for patentability set forth in Title 35 of the United States Code, 35 U.S.C. § 101, *et seq.*

### **FOURTH AFFIRMATIVE DEFENSE – PROSECUTION HISTORY ESTOPPEL**

4. The named inventor and/or The Boeing Company's representatives made representations to the United States Patent and Trademark Office ("PTO") whereby they surrendered subject matter for the purpose of overcoming rejection of the claims, thereby giving rise to prosecution history estoppel that excludes the accused products from the scope of the issued claims of the '412 patent.

#### **FIFTH AFFIRMATIVE DEFENSE – EQUITABLE ESTOPPEL**

5. Olympus's claims are barred by the doctrine of equitable estoppel such that Olympus cannot enforce the '412 patent against Given, or any of its customers, licensees or affiliates.

#### **SIXTH AFFIRMATIVE DEFENSE – LACHES**

6. Olympus's claims are barred by the doctrine of laches such that Olympus cannot recover any damages for alleged infringing activities before the filing of the Complaint.

#### **RESERVATION OF RIGHTS**

7. Given reserves the right to assert any and all additional affirmative defenses that may be determined during the course of discovery.

### **III. COUNTERCLAIMS**

Pursuant to Federal Rule of Civil Procedure 13, counterclaim plaintiffs Given Imaging Ltd. and Given Imaging, Inc. (collectively, "Given"), for their counterclaims against counterclaim defendants Olympus Corp., Olympus Medical and Olympus America (collectively, "Olympus"), aver as follows:

#### **THE PARTIES**

1. Given Imaging Ltd. is a company organized and existing under the laws of Israel, having its principal place of business at 2 Hacarmel Street, New Industrial Park, Yoqneam 20692, Israel.

2. Given Imaging, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 3950 Shackleford Road, Suite 500, Duluth, Georgia 30096-1852. It is a wholly-owned subsidiary of Given Imaging Ltd.

3. Upon information and belief, Olympus Corp. is a Japanese corporation with a principal place of business at 2-43-2 Hatagaya, Shibuy-ku, Tokyo 150-0072, Japan.

4. Upon information and belief, Olympus Medical is a Japanese corporation with a principal place of business at 2-43-2 Hatagaya, Shibuya-ku, Tokyo 150-0072, Japan, and is a wholly-owned subsidiary of Olympus Corp.

5. Upon information and belief, Olympus America is a New York corporation having a place of business at 3500 Corporate Parkway, Center Valley, Pennsylvania 18034-0610, and is a wholly-owned subsidiary of Olympus USA Incorporated, which, in turn, is a wholly-owned subsidiary of Olympus Corp.

#### **JURISDICTION AND VENUE**

6. These counterclaims arise under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Jurisdiction of this action is proper under 28 U.S.C. §§ 1331 and 1338(a), 1367, and 2201-02.

7. This Court has personal jurisdiction over counterclaim defendants because, *inter alia*, counterclaim defendants have submitted to the jurisdiction of this Court, and upon information and belief, conduct continuous and systematic business in the Commonwealth of Pennsylvania. Olympus America is a resident of the Commonwealth of Pennsylvania.

8. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b).

#### **JURY DEMAND**

9. Given demands a trial by jury pursuant to Fed. R. Civ. P. 38.

## **BACKGROUND**

10. Given Imaging Ltd. was founded in 1998, and was the first company in the world to develop, manufacture and market a capsule endoscopy system. Given pioneered the capsule endoscopy field, providing the first solution for imaging the entire small bowel, without surgery. Given obtained FDA clearance to market its small bowel capsule endoscope in the United States on August 1, 2001, and has done so since.

11. Given Imaging Ltd. is the lawful owner of all right, title, and interest in and to the following United States patents (“Given’s patents-in-suit”), including all right to sue and to recover for past infringement thereof:

A. United States Patent No. 5,604,531, entitled “IN VIVO VIDEO CAMERA SYSTEM” (“the ’531 patent”), a copy of which is attached hereto as Exhibit A, which was duly and legally issued February 18, 1997, naming Gavriel J. Iddan and Doron Sturlesi as the inventors.

B. United States Patent No. 6,934,093, entitled “OPTICAL SYSTEM” (“the ’093 patent”), a copy of which is attached hereto as Exhibit B, which was duly and legally issued August 23, 2005, naming Hanoch Kislev, Arkady Glukhovsky, Gavriel Meron, and Gavriel J. Iddan as the inventors.

C. United States Patent No. 7,022,067, entitled “SYSTEM AND METHOD FOR CONTROLLING IN VIVO CAMERA CAPTURE AND DISPLAY RATE” (“the ’067 patent”), a copy of which is attached hereto as Exhibit C, which was duly and legally issued April 4, 2006, naming Arkady Glukhovsky, Gavriel Meron, Doron Adler, Ofra Zinati, and Jerome Avron as the inventors.

D. United States Patent No. 7,119,814 entitled “SYSTEM AND METHOD FOR ANNOTATION ON A MOVING IMAGE” (“the ’814 patent”), a copy of



which is attached hereto as Exhibit D, which was duly and legally issued October 10, 2006, naming Gavriel Meron and Arkady Glukhovsky as the inventors.

12. Given Imaging, Inc. is a wholly-owned subsidiary of Given Imaging Ltd., is the U.S. distributor of Given's capsule endoscope products, and conducts sales, marketing and support activities.

13. Olympus alleges in Paragraph 22 of the Complaint that "Olympus has developed a capsule endoscope product that it intends to import into and sell in the United States within six months or less."

14. Olympus further alleges in Paragraph 23 of the Complaint that "Olympus has finalized the design of its capsule endoscope product and is nearing completion of clinical trials in order to secure clearance from the Food and Drug Administration, which Olympus expects to obtain."

15. Based on the foregoing, it is imminent that Olympus will infringe one or more claims of Given's patents-in-suit, and, thus, an actual and justiciable controversy exists between Given and Olympus with respect to Given's patents-in-suit.

#### **FIRST COUNTERCLAIM – NONINFRINGEMENT OF THE '412 PATENT**

16. Given repeats and realleges the allegations contained in Paragraphs 1-15 above, as if fully set forth herein.

17. Olympus alleges in Paragraphs 14 and 15 of the Complaint that:

A. "Upon information and belief, [Given Imaging Ltd.] has (or has caused to be) manufactured, imported into the stream of commerce of the United States and/or exported to the United States, capsule endoscopes with a light source that infringes, or the use of which infringes, one or more claims of the '412 patent."

B. “Upon information and belief, [Given Imaging, Inc.] has (or has caused to be) sold into the stream of commerce of the United States capsule endoscopes with a light source that infringes, or the use of which infringes, one or more claims of the ’412 patent.”

18. An actual controversy exists between Given and Olympus over the validity and infringement of the ’412 patent by virtue of Olympus’s allegation of infringement.

19. Given Imaging Ltd. does not infringe and has not infringed (either directly, contributorily or by inducement) any valid claim of the ’412 patent.

20. Given Imaging, Inc. does not infringe and has not infringed (either directly, contributorily or by inducement) any valid claim of the ’412 patent.

#### **SECOND COUNTERCLAIM – INVALIDITY OF THE ’412 PATENT**

21. Given repeats and realleges the allegations contained in Paragraphs 1-20 above, as if fully set forth herein.

22. One or more claims of the ’412 patent are invalid for failure to comply with one or more of the conditions and requirements for patentability set forth in Title 35 of the United States Code, 35 U.S.C. § 101, *et seq.*

#### **THIRD COUNTERCLAIM – INFRINGEMENT OF THE ’531 PATENT**

23. Given repeats and realleges the allegations contained in Paragraphs 1-22 above, as if fully set forth herein.

24. Olympus alleges in Paragraphs 28, 29, 30 and 31 of the Complaint that:

A. “the claims of the ’531 patent are invalid for failure to comply with the requirements of Title 35 U.S.C., including at least §§ 101, 102, 103 and/or 112.”

B. “it has not, and is not, infringing any claim of the ’531 patent and will not infringe any claims of that patent, by making, using, offering to sell or selling in the United States or importing into the U.S. its capsule endoscope product.”

C. “it has not induced or contributed to, and is not inducing or contributing to, the infringement of any claim of the ’531 patent and Olympus will not induce or contribute to the infringement of any claim of that patent by making, using, offering to sell or selling in the United States or importing into the U.S. its capsule endoscope product.”

D. “Given Imaging is barred by prosecution history estoppel from asserting that Olympus’s capsule endoscope product infringes one or more claims of the ’531 patent.”

25. An actual controversy exists between Given and Olympus over the validity and infringement of the ’531 patent by virtue of Olympus’s allegations.

26. Upon information and belief, Olympus Corp.’s manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’531 patent.

27. Upon information and belief, Olympus Medical’s manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’531 patent.

28. Upon information and belief, Olympus America’s manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’531 patent.

29. Upon information and belief, Olympus's infringement of the '531 patent, if permitted, will cause damage to Given and, unless enjoined by this Court, irreparable injury.

30. Upon information and belief, Olympus has been aware of the existence of the '531 patent, but nevertheless will be infringing one or more claims of the '531 patent. This infringement by Olympus will be willful and deliberate and in disregard of Given's lawful rights under the '531 patent.

31. Upon information and belief, Olympus has no reasonable basis for believing that Olympus's capsule endoscope and/or its associated system will not infringe the '531 patent, thus rendering the case "exceptional," as that term is set forth in 35 U.S.C. § 285.

#### **FOURTH COUNTERCLAIM – INFRINGEMENT OF THE '093 PATENT**

32. Given repeats and realleges the allegations contained in Paragraphs 1-31 above, as if fully set forth herein.

33. Upon information and belief, Olympus Corp.'s manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '093 patent.

34. Upon information and belief, Olympus Medical's manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '093 patent.

35. Upon information and belief, Olympus America's manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '093 patent.

36. Upon information and belief, Olympus's infringement of the '093 patent, if permitted, will cause damage to Given and, unless enjoined by this Court, irreparable injury.

37. Upon information and belief, Olympus has been aware of the existence of the '093 patent, but nevertheless will be infringing one or more claims of the '093 patent. This infringement by Olympus will be willful and deliberate and in disregard of Given's lawful rights under the '093 patent.

38. Upon information and belief, Olympus has no reasonable basis for believing that Olympus's capsule endoscope and/or its associated system will not infringe the '093 patent, thus rendering the case "exceptional," as that term is set forth in 35 U.S.C. § 285.

#### **FIFTH COUNTERCLAIM – INFRINGEMENT OF THE '067 PATENT**

39. Given repeats and realleges the allegations contained in Paragraphs 1-38 above, as if fully set forth herein.

40. Upon information and belief, Olympus Corp.'s manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '067 patent.

41. Upon information and belief, Olympus Medical's manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '067 patent.

42. Upon information and belief, Olympus America's manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '067 patent.

43. Upon information and belief, Olympus's infringement of the '067 patent, if permitted, will cause damage to Given and, unless enjoined by this Court, irreparable injury.

44. Upon information and belief, Olympus has been aware of the existence of the '067 patent, but nevertheless will be infringing one or more claims of the '067 patent. This infringement by Olympus will be willful and deliberate and in disregard of Given's lawful rights under the '067 patent.

45. Upon information and belief, Olympus has no reasonable basis for believing that Olympus's capsule endoscope and/or its associated system will not infringe the '067 patent, thus rendering the case "exceptional," as that term is set forth in 35 U.S.C. § 285.

#### **SIXTH COUNTERCLAIM – INFRINGEMENT OF THE '814 PATENT**

46. Given repeats and realleges the allegations contained in Paragraphs 1-45 above, as if fully set forth herein.

47. Upon information and belief, Olympus Corp.'s manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '814 patent.

48. Upon information and belief, Olympus Medical's manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '814 patent.

49. Upon information and belief, Olympus America's manufacture, use, sale, offer for sale, and/or importation into the United States of its capsule endoscope and/or its associated system will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '814 patent.

50. Upon information and belief, Olympus's infringement of the '814 patent, if permitted, will cause damage to Given and, unless enjoined by this Court, irreparable injury.

51. Upon information and belief, Olympus has been aware of the existence of the '814 patent and the published application that led to that patent, but nevertheless will be infringing one or more claims of the '814 patent. This infringement by Olympus will be willful and deliberate and in disregard of Given's lawful rights under the '814 patent.

52. Upon information and belief, Olympus has no reasonable basis for believing that Olympus's capsule endoscope and/or its associated system will not infringe the '814 patent, thus rendering the case "exceptional," as that term is set forth in 35 U.S.C. § 285.

#### **IV. PRAYER FOR RELIEF**

WHEREFORE, Given prays for judgment against plaintiffs/counterclaim defendants as follows:

- A. Adjudging that the '412 patent is invalid;
- B. Adjudging that the '412 patent is not infringed by either Given Imaging Ltd. or Given Imaging, Inc.;
- C. Adjudging that the '531, '093, '067 and '814 patents are valid and enforceable;
- D. Adjudging that Olympus will infringe the '531, '093, '067 and '814 patents, and that such infringement will be willful;
- E. Preliminarily and permanently enjoining Olympus, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States,

or importation into the United States, of any product that infringes the '531, '093, '067 and '814 patents;

F. Declaring this an exceptional case and awarding Given its attorney fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

G. Awarding Given such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Dated: October 20, 2006

By: /s/ H. Robert Fiebach, James G. Lare

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**CERTIFICATE OF SERVICE**

I, James G. Lare, Esquire, hereby certify that on October 20, 2006, I electronically filed Given Imaging Ltd.'s and Given Imaging, Inc.'s Answer and Counterclaims via the Court's Electronic Case Filing system and served a true and correct copy of same via first class, regular mail on the following:

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\_\_\_\_\_  
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